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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
LEA, CHRISTOPHER RAYMOND				
ART UNIT		PAPER NUMBER		
4161				
NOTIFICATION DATE		DELIVERY MODE		
07/28/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/534,543

Applicant(s)

AUWETER ET AL.

Examiner

Christopher R. Lea

Art Unit

4161

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date 5/10/05 & 6/05/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This application is a 371 (national stage application) of PCT/EP03/012557.

Claims 1-12, 14, & 16 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-9 & 16, in the reply filed on May 28, 2008, is acknowledged. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctiveness and that no evidence of a search burden has been presented. This is not found persuasive because applicant is arguing an inappropriate restriction standard.

The Examiner has properly applied the standard of unity of invention that governs this application. This application is a national stage filing of a PCT application under 35 USC 371. 35 USC 372 (a)(2) provides authority to evaluate unity of invention:

[T]he Director may cause the question of unity of invention to be reexamined under section 121 of this title, within the scope of the requirements of the treaty and the Regulations;

As such, all claims of the application must be examined together as long as there is unity of invention as defined in Patent Cooperation Treaty Rule 13.2 and 37 CFR 1.475(a):

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Examiner has determined that the instant application lacks unity of invention because claim 1 does not define a contribution over the prior art. Since claim 1 does not define a contribution over the prior art, it does not possess a special technical feature; since it does not possess a special technical feature, it cannot share a special technical feature with the other inventions; therefore, the instant application lacks unity of invention. Under these circumstances, restriction is proper as outlined in 37 CFR 1.499:

If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under §§ 1.143 and 1.144.

As such the restriction requirement is deemed proper and made FINAL.

2. Claims 10-12 & 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 28, 2008.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on May 10, 2005, and June 5, 2006, were filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. The IDS filed May 10, 2005, does not comply with the provisions of 37 CFR 1.98 in that no translation or

explanation of relevance has been provided for French language document FR 2 817 478; therefore, this document has not been considered. Accordingly, the remaining references on the information disclosure statements are being considered by the examiner.

Claim Objections

5. Claim 1 is objected to because of the following informalities: Claim 1 recites the limitation "...having mean particle size of from 0.05 to 1, wherein..." It is unclear what units are being used for the size: nanometers, micrometers, millimeters, or some other unit? For the purposes of examination, it will be assumed to be micrometers, since the range of 0.05-1 μm is supported in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 7-9 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dolhaine et al. (US Patent 6,352,737).

Claim 1: Dolhaine et al. teach a phytosterols (column 2 lines 22-29) in nanoparticle formulation of size 50-150 nm (0.05-0.15 μm , column 2, lines 1-3). Nanoparticles are by definition a fine powder (pulverulent).

Claims 2 & 9: Since the formulation of claim 1 is anticipated in the prior art, the instantly claimed properties, degree of crystallinity and water dispersibility, are

Art Unit: 4161

anticipated as well. "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established" (See *In re Best* and MPEP § 2112.01).

Claim 3: Dolhaine et al. teach adding a protective colloid to the formulation (column 3 lines 4-14)

Claim 4: Dolhaine et al. teach a formulation containing 20% phytosterol (by dry weight, example 6, column 4 lines 16-26).

Claim 5: Dolhaine et al. teach a formulation containing 20% phytosterol (by dry weight, example 6, column 4 lines 16-26). Dolhaine et al. teach adding a protective colloid to the formulation in amounts of 5 to 15% by weight (column 3 lines 4-14).

Claim 7: Dolhaine et al. teach adding emulsifiers to the formulation in amounts of 5 to 15% by weight (column 3 lines 4-14)

Claim 8: Dolhaine et al. teach adding 0.4% tocopherol, an antioxidant, to the formulation (examples 1-2 in column 3 line 65 through column 4 line 46, including table 1).

Claim 16: Dolhaine et al. teach using the phytosterol nanoparticles in food products (column 3 lines 52-60).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 4161

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 & 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dolhaine et al. (US Patent 6,352,737) in view of Auriou (US PreGrant Publication 2003/0165572)..

Claim 6 is dependent from claim 1; therefore, rejection of claim 1 under 35 U.S.C. 103(a) is also appropriate. Discussion of the contents of Dolhaine et al. appears in the 102 section *supra*.

Dolhaine et al. does not teach adding plasticizers to the phytosterol formulation. This deficiency in Dolhaine et al. is cured by the teachings of Auriou.

Auriou teaches, as a whole, a phytosterol powdery formulations (particle size 50+ μm). Auriou teaches adding excipients, such as dextrose (glucose) and lactose, to the phytosterol formulation in amounts of 1-50% by weight (paragraph 29). These excipients are among the listed plasticizers in the instant specification.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to combine smaller particle size of

Dolhaine et al. with the phytosterol formulation of Auriou because Auriou states that "[t]he smaller the particle size, the better dispersion obtained and the less 'sandy' the feeling in the mouth."

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. R. L./
Examiner, Art Unit 4161

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161